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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PATTERSON, MARC A	

ART UNIT	PAPER NUMBER
1772	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/733,079	**Applicant(s)** ANDERSSON ET AL.	
	Examiner Marc A. Patterson	**Art Unit** 1772	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *none*.
   Claim(s) objected to: *1-34*.
   Claim(s) rejected: *1-9,11-14 and 16-34*.
   Claim(s) withdrawn from consideration: *none*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See attached.

ADVISORY ACTION

ANSWERS TO APPLICANT'S AMENDMENTS

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1 – 9, 11 – 14, 16 – 17 and 20 – 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al in (U.S. Patent No. 5,783,269) view of Collette et al (U.K. Patent 2001080) and Fujii et al (European Patent No. 0838321).

With regard to Claims 1, 11 – 14 and 16 – 17, Heilmann et al disclose a film comprising three layers, an outer layer, supporting layer and a middle layer bctween the two layers (the middle layer is termed the central layer; column 3, lines 31 - 32); the outer layer and supporting layer are identical (column 3, lines 31 - 32) the supporting layer is therefore an inner layer, opposite the outer layer, having the same composition; the outer layer comprises polypropylene alone (column 5, lines 30 – 35) and the middle layer comprises polypropylene or a polypropylene blend (column 5, lines 43 - 45) and the inner layer consists of polypropylene (column 5, lines 46 – 50); the three layers therefore consist of 100% polypropylene materials; the film is sterilized with hot steam at 121 degrees Celsius (column 9, lines 14 - 16). Heilmann et al fail to disclose a laminate that displays no measurable yield point.

Collette et al teach a polypropylene (page 1, line 5) that shows no yield point, and therefore displays no measurable yield point (page 1, line 54) for use in the making of films

(page 4, lines 18 - 19) for the purpose of obtaining films having high extensibility (page 4, line 25). One of ordinary skill in the art would therefore have recognized the advantage of providing for the polypropylene of Colette et al which displays no measurable yield point, as the polypropylene in Heilmann et al, depending on the desired extensibility of the end product. It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a polypropylene which displays no measurable yield point in Heilmann et al in order to obtain a film having high extensibility as taught by Colette et al, thus obtaining a multi – layer film having no measurable yield point; the film taught by Collette et al displays no yield following exposure to temperature above l21 degrees Celsius (after hot compression molding at 180 degrees Celsius; page 9, lines 51 - 55) and therefore displays no yield following sterilization at 121 degrees Celsius.

Heilmann et al also fail to disclose a film having an elasticity modulus of the middle layer that is less than 100 MPa and an elasticity modulus of the material of the outer layer that is greater than 400 MPa.

Fujii et al teach a polypropylene film (sheet; page 29 - 30) having an elasticity modulus (elastic modulus; page 4, lines 31 - 32) of 20 to 1000 MPa (page 2, line 39) for the purpose of obtaining a film that is soft and transparent (page 4, line 29). One of ordinary skill in the art would therefore have recognized the advantage of providing for the modulus of elasticity of 20 to 1000 MPa of Fujii et al in the layers of Heilmann et al and Colette et al, which comprises a polypropylene film, depending on the desired softness and transparency of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for an elasticity modulus (elastic modulus',

page 4, lines 31 - 32) of 20 to 1000 MPa in Heilmann et al and Colette et al in order to obtain a film that is soft and transparent as taught by Fujii et al. The range of elasticity moduli of the layers would therefore include the claimed ranges of less than 100 MPa and greater than 400 MPa.

With regard to Claims 2 – 4, the proportion of the thickness represented by the middle layer is 70% (column 4, lines 8 - 17).

With regard to Claims 5 - 6, the proportion of the thickness represented by each of the outer layer and inner layer is 15% (column 4, lines 8 - 1 3).

With regard to Claim 7, the total thickness of the film is 130 μm (column 4, lines 8 – 13).

With regard to Claims 8 – 9, Heilmann et al fail to disclose a total thickness in the range between 170 and 230 μm. However, Heilmann et al disclose a middle layer thickness of at least 90 μm (column 4, lines 10 – 11) and teaches the selection of layer thickness to avoid deformation of the middle layer under the action of heat (column 4, lines 13 - 17). Therefore, one of ordinary skill in the art would have recognized the utility of varying the thicknesses of the layers of the film, and therefore the total thickness of the film, to limit the deformation of the middle layer as desired. Therefore, the deformation of the middle layer would be readily determined through routine optimization of thickness by one having ordinary skill in the art depending on the end use of the product.

It therefore would be obvious for one of ordinary skill in the art to vary the thickness in order to obtain a desired limiting of the deformation of the middle layer, since the limiting of the deformation of the middle layer would be readily determined through routine optimization by

one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claim 18, Heilmann et al fail to disclose an outer layer having a melting point that is greater than the melting point of the inner layer. However, Heilmann et al disclose that both layers contain polymers having melting temperatures greater than 1 21 degrees Celsius (column 4, lines 4 - 7) and that the melting point is selected so that the outer and inner layers support and stabilize the middle layer (column 3, lines 40 - 42). Therefore one of ordinary skill in the art would have recognized the utility of varying the melting temperatures of the polymers to obtain a desired stability of the middle layer. Therefore, the desired stability of the middle layer would be readily determined through routine optimization of the melting temperature of the polymers by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the melting temperatures of the polymers in order to obtain a desired stability of the middle layer, since the stability of the middle layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claim 19, Heilmann et al fail to disclose a melting point of the middle layer that is less than the melting point of the outer layer and greater than the melting point of the inner layer. However, Heilmann et al disclose an outer and inner layer comprising polymers that have a softening temperature greater than 121 degrees Celsius and polymers that have a softening point less than 121 degrees Celsius (the layers adjacent to the central layer have a sohening temperature of greater than 121 degrees Celsius or contains polymers having a softening temperature of greater than 121 degrees Celsius, column 4, lines 4 - 7) and Heilmann

et al teach that the softening temperatures are selected in order for the outer and inner layers to provide desired support to the middle layer (column 3, lines 62 – 67; column 1, lines 1 - 3). Therefore, one of ordinary skill in the art would have recognized the utility of varying the softening temperature of the components having a softening temperature less than 121 degrees Celsius to provide desired support to the middle layer. Therefore, the desired support provided to the middle layer would be readily determined through routine optimization of softening temperature by onehaving ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the softening temperature of the components having a softening temperature less than 121 degrees Celsius in the outer and inner layers, and therefore the lowest melting temperature of the outer and inner layers, and therefore the melting point of the outer and inner layers, in order to provide desired support to the middle layer, since the support to the middle layer would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claims 20 - 22, the middle layer disclosed by Heilmann et al has a Vicat temperature of 55 degrees Celsius (Vicat A = 55 degrees Celsius; column 8, lines 11 - 15), which is in the range from 35 degrees Celsius to 75 degrees Celsius. Heilmann et al also disclose outer layers and inner layers having Vicat temperatures of less than 121 degrees C, as discussed above (the layers adjacent to the central layer have a softening temperature, therefore a Vicat temperature, of greater than 121 degrees Celsius or contains polymers having a softening temperature of greater than 121 degrees Celsius; column 4, lines 4 - 7).

With regard to Claim 23, as discussed above with regard to Claim 1, the outer layer, middle layer and inner layer disclosed by Heilmann et al consist of polypropylene; the polypropylene is polypropylene homopolymer, in the outer layer (column 5, line 30), middle layer (column 5, line 39) and inner layer (column 5, line 48).

With regard to Claim 24, Heilmann et al fail to disclose a layer that consists of 70 - 90% polypropylene homopolymer. However, Heilmann et al disclose an inner layer consisting of polypropylene homopolymer, as discussed above, and Heilmann et al teach that the composition of the inner layer is selected to provide flexibility and clarity to the inner layer (column 5, lines 24 – 29). Therefore one of ordinary skill in the art would have recognized the utility of varying the amount of polypropylene to obtain a desired flexibility and clarity. Therefore, the flexibility and clarity would be readily determined through routine optimization of the amount of polypropylene by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the amount of polypropylene in order to obtain a desired flexibility and clarity, since the flexibility and clarity would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claim 25, the middle layer disclosed by Heilmann et al comprises styrene - ethylene / butylene - styrene block copolymer (column 5, lines 36 - 41) and Heilmann et al teach that the inner layer comprises 70% by weight of the composition of the middle layer, to improve adhesion between the two layers (column 6, lines 1 - 6). Heilmann et al fail to disclose an inner layer comprising 10 - 30% by weight styrene - ethylene / butylene - styrene block

copolymer. However, Heilmann et al teach the selection of the amount of styrene - ethylene / butylene - styrene block copolymer to improve adhesion between the two layers (column 6, lines 1 - 6). Therefore, one of ordinary skill in the art would have recognized the utility of varying the amount of styrene - ethylene / butylene - styrene block copolymer to obtain a desired adhesion. Therefore, the adhesion would be readily determined through routine optimization of the amount of styrene - ethylene / butylene - styrene block copolymer by one having ordinary skill in the art depending on the desired end use of the product. It therefore would be obvious for one of ordinary skill in the art to vary the amount of styrene - ethylene / butylene - styrene block copolymer in order to obtain a desired adhesion, since the adhesion would be readily determined through routine optimization by one having ordinary skill in the art depending on the desired end result as shown by Heilmann et al.

With regard to Claim 26, Heilmann et al also disclose a five layer film (column 3, line 62) comprising two layers having the composition of the middle layer and a layer having a polymer with a softening temperature of above 121 degrees Celsius between the two layers (column 3, lines 62 – 67; column 4, lines 1 – 3) and discloses that the outer and inner layers contain polymers having softening temperatures above 121 degrees Celsius (column 3, lines 31 - 36); Heilmann et al therefore disclose a five layer film having the multilayer structure: outer layer, middle layer, outer layer, middle layer, inner layer, with the thicknesses of the middle layers and outer layers being the sum of the thicknesses of the middle layers and outer layers.

With regard to Claim 27, Heilmann et al also disclose a seven layer film (column 3, line 62) comprising three layers having the composition of the middle layer and two layers having a polymer with a softening temperature of 121 degrees Celsius arranged between the three layers

(column 3, lines 62 – 67; column 4, lines 1 – 3) and discloses that the outer and inner layers contain polymers having softening points above 121 degrees Celsius (column 3, lines 31 - 36),. Heilmann et al therefore disclose a seven layer film having the multilayer structure: outer layer, middle layer, outer layer, middle layer, outer layer, middle layer, inner layer, with the thicknesses of the middle layers and outer layers being the sum of the thicknesses of the middle layers and outer layers.

With regard to Claim 28, Heilmann et al disclose a method of producing the film comprising co - extruding the layers (column 6, lines 17 - 21).

With regard to Claims 29 – 31, the film disclosed by Heilmann et al is co – extruded as a flat film (column 6, lines 15 - 16); the film is therefore joined as a flat film, because in the process of co - extrusion the layers are joined to form the multi - layer film.

With regard to Claim 32, the film disclosed by Heilmann et al is suitable for contact with foodstuffs (column 7, lines 64 - 66) and Heilmann et al discloses that the use of multi - layer films in the packaging of foodstuffs (column 1, lines 16 - 20); Heilmann et al therefore disclose a packaging comprising the disclosed film.

With regard to Claim 33, the packaging stores parenteral solutions (it is appropriately sutiable for contact with parenteral solutions', column 7, lines 64 - 67), and also stores water (it is formed into a bag which is filled with water; column 8, lines 58 - 63) and therefore stores water.

3. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al. (U.S. Patent No. 5,783,269) in view of Collette et al (U.K. Patent 2001080) and Fujii et al

(European Patent No. 0838321) and further in view of Andersson et al (U.S. Patent No. 6,322,739 B1).

Heilmann et al, Colette et al and Fujii et al disclose packaging comprising polypropylene as discussed above. Heilmann et al, Colette et al and Fujii et al fail to disclose a packaging that stores fluid lipophilic emulsions.

Andersson et al teach a packaging (a container having stored fluid; column 4, lines 67) comprising polypropylene (column 4, lines 39 - 41) that stores fluid lipophilic emulsions (column 3, lines 20 - 23) for the purpose of obtaining a package having good compatibility with fluid lipid emulsions (column 3, lines 20 - 21). One of ordinary skill in the art would therefore have recognized the advantage of providing for the packaging of Andersson et al that stores fluid lipophilic emulsions, in Heilmann et al, Colette et al and Fujii et al, which is a packaging comprising polypropylene, depending on the desired compatibility of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a packaging that stores fluid lipophilic emulsions in Heilmann et al, Colette et al and Fujii et al in order to obtain a package having good compatibility as taught by Andersson et al.

ANSWERS TO APPLICANT'S ARGUMENTS

4. Applicant's arguments Applicant's arguments regarding the 35 U.S.C. 103(a) rejection of Claims 1 – 9, 14 and 20 – 33 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Collette et al (U.K. Patent 2001080), 35 U.S.C. 103(a) rejection of Claims 10 – 13 and 15 – 17 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in

view of Collette et al (U.K. Patent 2001080) and further in view of Fujii et al (European Patent No. 0838321), and 35 U.S.C. 103(a) rejection of Claims 10 – 13 and 15 – 17 as being unpatentable over Heilmann et al (U.S. Patent No. 5,783,269) in view of Collette et al (U.K. Patent 2001080) and further in view of Andersson et al (U.S. Patent No. 6,322,739 B1), of record in the previous Action, have been carefully considered but have not been found to be persuasive for the reasons discussed below.

Applicant argues, on page 6 of the remarks dated September 27, 2005, that Heilmann et al fail to disclose a film having no measurable yield point.

However, as stated on page 2 of the previous Action, a film having no measurable yield point is taught by Collette et al.

Applicant also argues on page 6 there is no suggestion in Heilmann or Colette et al that the claimed modulus of elasticity can be used to achieve a superior multi – layer film or that a middle layer film can be produced having the claimed modulus of elasticity.

However, as stated above, the claimed modulus of elasticity is taught by Fujii et al; furthermore, a superior film is not claimed, and the meaning of the term 'superior' as used by Applicant is unclear.

Applicant also argues, on page 7, that Collette et al is not concerned with a medical bag, and that there are no hints with regard to the claimed improvements.

However, as stated on page 3 of the previous Action, both Heilmann et al and Collette et al are directed to articles comprising multilayer films, therefore there is suggestion to utilize the Collette et al polymers in Heilmann et al; furthermore, it is unclear what improvements are being referred to.

Applicant also argues, on page 7, that knowledge of Colette et al would not suggest a multi – layer film.

However, as stated above, both Heilmann et al and Collette et al are directed to articles comprising multilayer films, therefore there is suggestion to utilize the Collette et al polymers in Heilmann et al

Applicant also argues, on page 7, that there is no suggestion in Fujii et al of a multilayer film having no yield.

However, as stated on page 3 of the previous Action, Fujii et al is utilized only for the teaching that the claimed modulus is known in the art for a polypropylene film, for the purpose of making a film that is soft; furthermore, a polypropylene film having no yield is taught by Colette et al.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc A Patterson whose telephone number is 571-272-1497. The examiner can normally be reached on Mon - Fri 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marc Patterson 12/12/05

Marc A. Patterson, PhD.
Examiner
Art Unit 1772